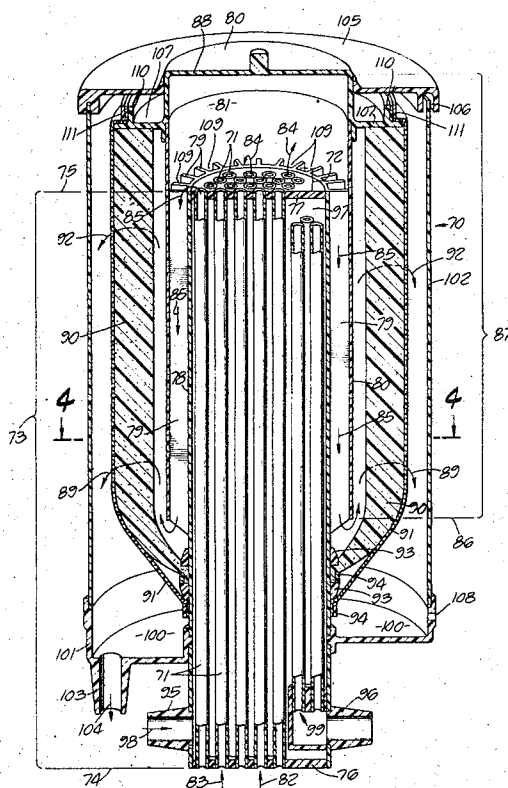


[54] **A BUBBLE OXYGENERATOR INCLUDING
A BLOOD FOAM RETURN EXCHANGER
DEVICE**[75] Inventors: **Robert C. Brumfield**, Laguna
Beach; **Edward E. Simmons**,
Pasadena, both of Calif.[73] Assignee: **William Harvey Research
Corporation**, Santa Ana, Calif.[22] Filed: **June 5, 1972**[21] Appl. No.: **259,713**[52] U.S. Cl. **23/258.5, 55/255, 55/256,**
128/400, 128/DIG. 3, 261/122, 261/124[51] Int. Cl. **A61m 1/03**[58] Field of Search 23/258.5; 128/DIG. 3, 400;
261/122-128; 55/255, 256; 195/1.8[56] **References Cited****UNITED STATES PATENTS**

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Primary Examiner—Barry S. Richman
Attorney, Agent, or Firm—J. L. Jones, Sr.[57] **ABSTRACT**

A blood foam return exchanger device provides multiple fluid flow guidance channels disposed around the exterior of a blood-oxygen fluid exchanger having multiple oxygenator tubes. The guidance channels, formed by multiple fins disposed parallel to the tubular axis of symmetry of the fluid exchanger, provide additional residence time in the fluid flow channels for the gaseous exchange of the oxygen gas-blood two-phase mixture while descending the channels. The return shell has a return cap terminus disposed a spaced holding chamber volume above the top header plate of the exchanger, turning the blood foam flow downward 180° after ascending the oxygenator tubes. The multiple fins can provide heat exchange surfaces for further precise temperature control of the blood foam. The blood foam exiting from the return exchanger device flows through the surrounding defoamer filter, separating foam into blood and exchanged gases. A relatively short fluid exchanger utilizes the additional blood foam residence time provided by the guidance channels. Still another blood foam return exchanger device has an integral 180° U-bend return loop extension on each oxygenator tube of the fluid exchanger, and an oxygenator tube return length interiorly extending adjacently down the internal perimeter of the heat exchanger boundary case. Each exit terminus of an oxygenator tube return length extends through the exchanger boundary case, providing an exit for the blood foam into and through the surrounding annular defoamer filter.

10 Claims, 8 Drawing Figures

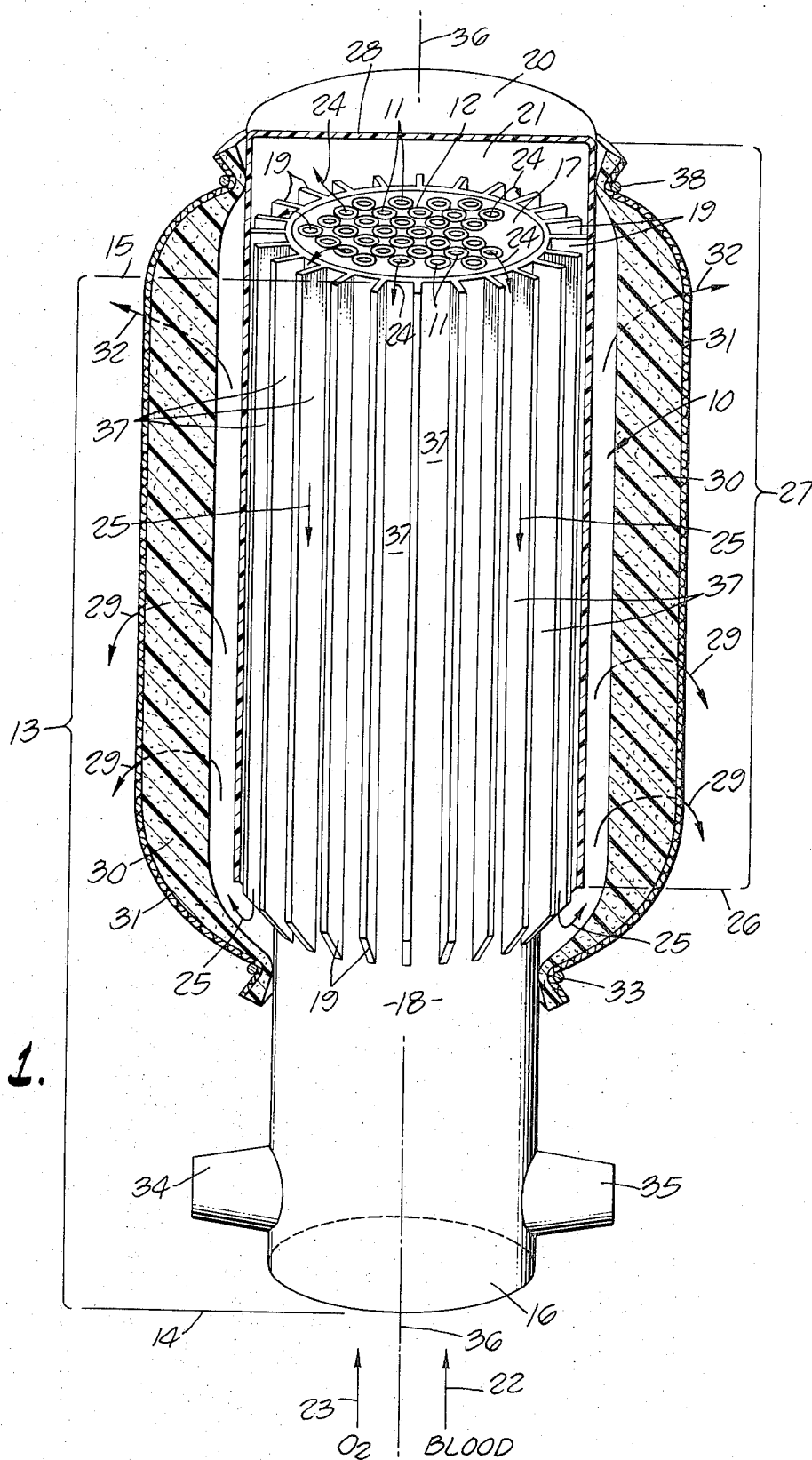


FIG. 1.

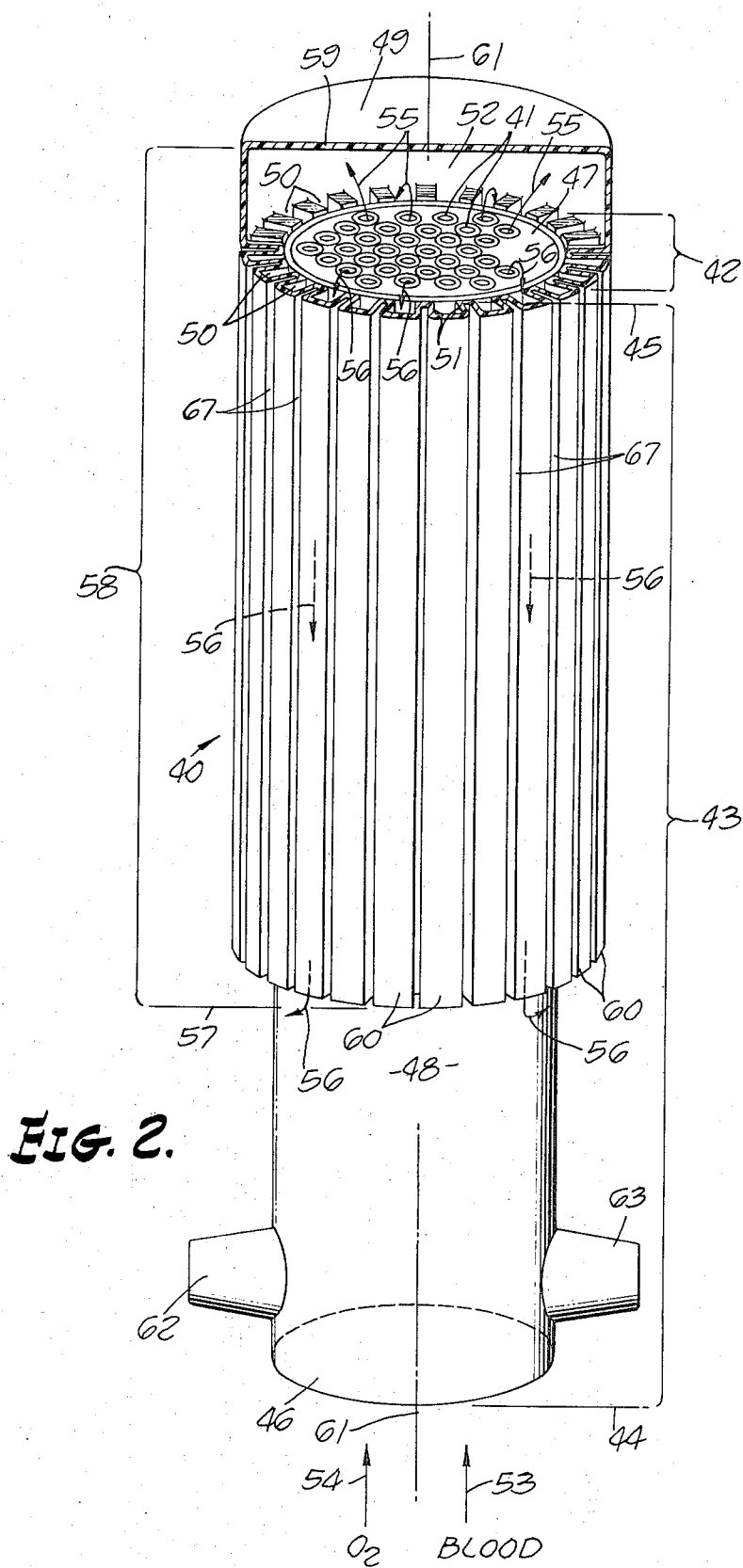
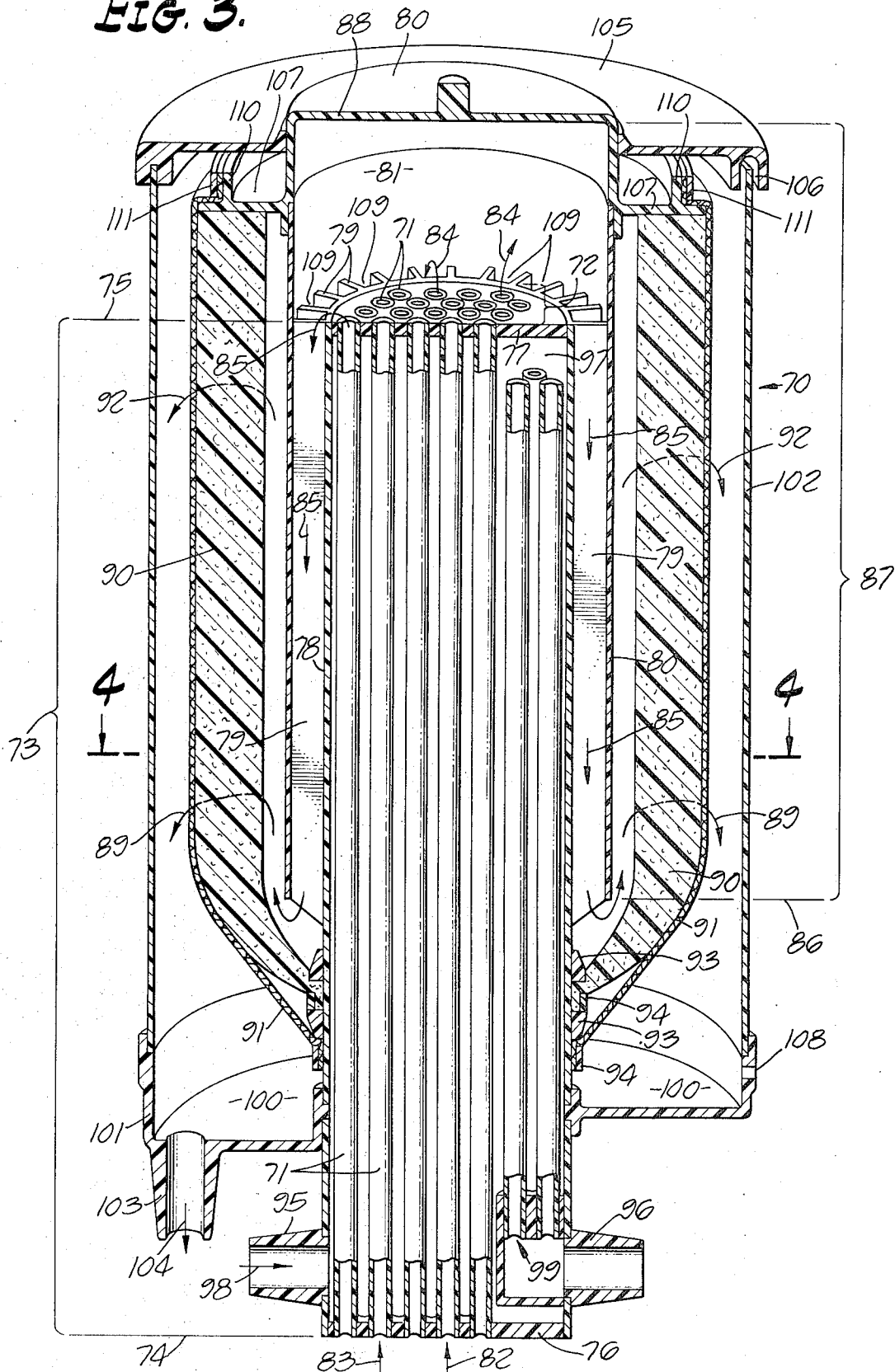


FIG. 3.



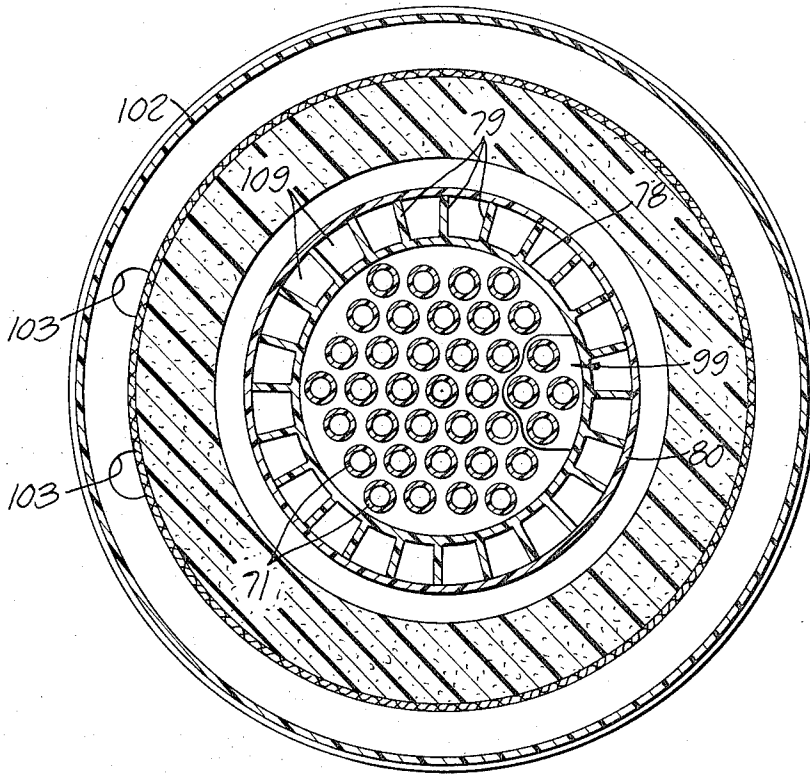


FIG. 4.

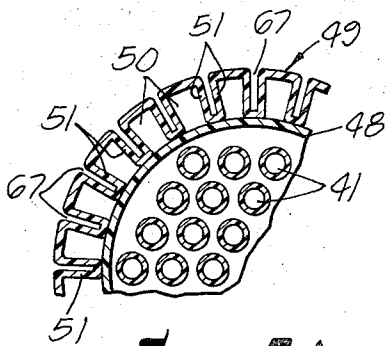


FIG. 5A.

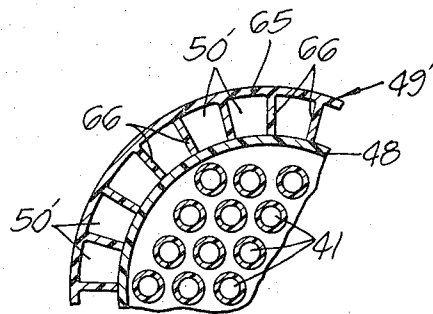
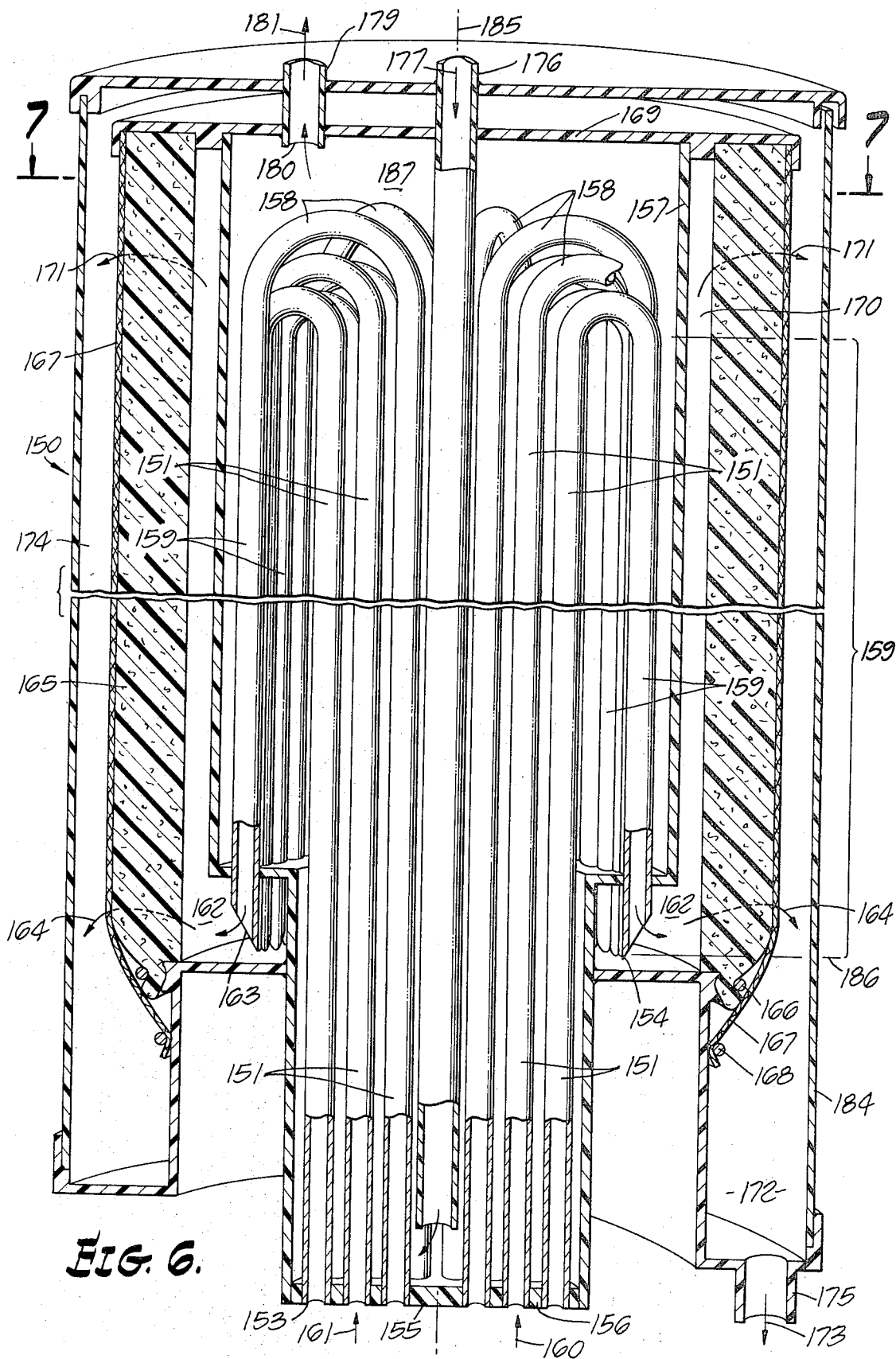


FIG. 5B.



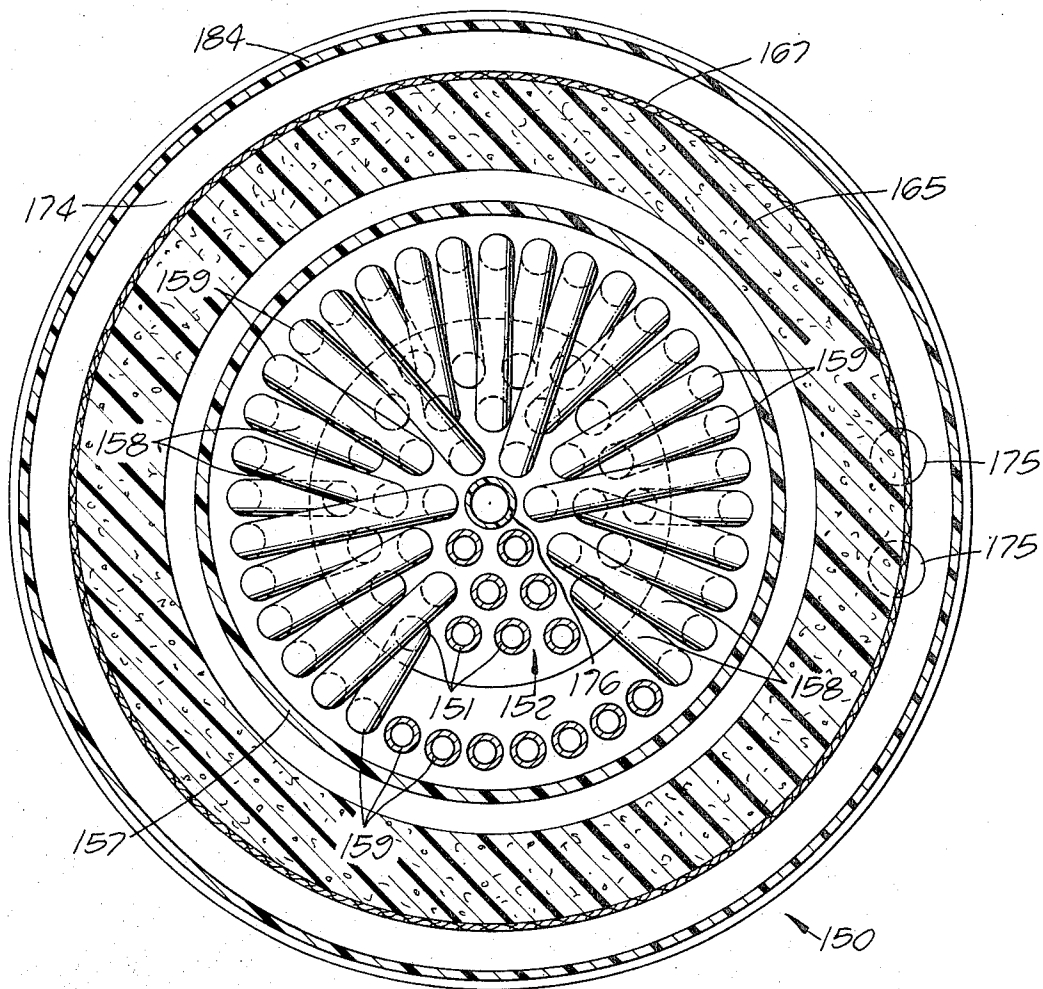


FIG. 7

A BUBBLE OXYGENATOR INCLUDING A BLOOD FOAM RETURN EXCHANGER DEVICE

CROSS REFERENCES TO RELATED APPLICATIONS

This application is related to the following applications filed earlier by the sole inventor, Robert C. Brumfield:

U.S. patent application, Ser. No. 175,182 for BLOOD OXYGENATOR AND THERMOREGULATOR APPARATUS, by Robert C. Brumfield, filed Aug. 26, 1971; now U.S. Pat. No. 3,769,162;

U.S. patent application, Ser. No. 196,458 for BLOOD OXYGENATOR FLOW GUIDE, by Robert C. Brumfield, filed Nov. 11, 1971; now U.S. Pat. No. 3,769,163;

U.S. patent application, Ser. No. 202,779 for TWO-PHASE FLUID FLOW GUIDE FOR BLOOD OXYGENATOR, by Robert C. Brumfield, filed Nov. 29, 1971; now U.S. Pat. No. 3,770,384;

U.S. patent application, Ser. No. 216,649 for LOW PRESSURE HEAT EXCHANGER FOR OXYGENATED BLOOD, by Robert C. Brumfield, filed Jan. 10, 1972; now U.S. Pat. No. 3,764,271; and the application by the co-inventors,

U.S. patent application, Ser. No. 240,054 for INTEGRAL BLOOD OXYGENATOR AND HEAT EXCHANGER, by Robert C. Brumfield and Alton V. Hooper, filed Mar. 31, 1972; now U.S. Pat. No. 3,768,977, and assigned to Robert C. Brumfield.

BACKGROUND OF THE INVENTION

Blood oxygenators and blood temperature controllers useful for oxygenating patient's blood in extra-corporeal circulation are classified in Class 23 Subclass 25.8.5. The improvement taught in this invention is also so classified.

Fuson, in U.S. Pat. No. 3,064,649, issued Nov. 20, 1962, discloses a blood filter and a separate heat exchanger apparatus for use with extra-corporeal blood circulating apparatus. The mechanically separate heat exchanger and blood filter are serially connected. The heat exchanger is taught for the induction of hypothermia, a conventional separate oxygenator being disclosed in the specification.

DeWall in U.S. Pat. No. 3,256,883, issued June 21, 1966, discloses a two dimensional envelope or bag-type oxygenator comprised in large part of thermoplastic resinous sheet material sealed together. The temperature control or heat exchanger means shown is in the form of a channeled internal water jacket, which is heat sealed between walls of the oxygenator in the vicinity of multiple blood channels or conduits, warming or cooling the blood as it passes through those channels. Specifically, this invention teaches the first step of oxygenating the blood at a relatively uncontrolled blood temperature, and then effectively controlling the blood temperature in a second step by circulating the blood through a heat exchanger.

Claff et al. in U.S. Pat. No. 3,332,746, issued July 25, 1967, discloses a pulsatile membrane apparatus for oxygenating blood, disclosing a separate heat exchange fluid source which circulates through the oxygenator. Grooved metal plates in combination with the externally pumped heat exchange fluid provide a heat transfer energy input or output source for the blood circulat-

ing in the oxygenator. The oxygenation of the blood proceeds by diffusion through a suitable membrane.

Farrant, in U.S. Pat. No. 3,374,066, issued Mar. 19, 1968, teaches a separately operable thermostabilizer for an extra-corporeal oxygenator of blood. A separate conventional blood oxygenator system is disclosed providing for the oxygenation of the blood, and a separate individual heat exchanger is taught for the thermostabilization of the blood temperature.

The subject invention teaches a blood foam return exchanger device for an integral blood oxygenator and heat exchanger, providing a relatively short fluid exchanger providing the required blood foam residence time. Additionally, the device provides concurrent heat transfer agent flow useful for temperature control in the fluid exchanger, and counter-current heat flow in the blood foam return exchanger device, for precise temperature control of the blood during extra-corporeal circulation.

SUMMARY OF THE INVENTION

A blood foam return exchanger device disposed on an integral blood oxygenator and heat exchanger combination operationally insures that extra-corporeal blood is circulated, oxygenated and concurrently precisely temperature controlled prior to return to a patient's body. In the cross-reference application Ser. No. 240,054, filed Mar. 31, 1972, and other earlier filed extra-corporeal blood oxygenator and blood temperature controller was disclosed and taught, having a patterned array of multiple small diameter, equal length oxygenator tubes disposed in a top and bottom pair of fluid impervious header plates, in a fluid exchanger configuration.

A tubular return shell provides multiple fluid flow guidance channels disposed around the exterior of a blood-oxygen fluid exchanger having multiple oxygenator tubes. The guidance channels are formed in part by multiple fins disposed parallel to the tubular axis of symmetry of the exchanger, providing additional residence time in the fluid flow channels for the gaseous exchange between oxygen gas-blood two-phase mixture while descending the guidance channels. The return shell has a return cap terminus disposed a spaced holding chamber volume above the top header plate of the exchanger, turning the blood foam flow downward 180°, after ascending the oxygenator tubes. The multiple fins provide additional heat exchange surfaces for further precise temperature control of the blood foam. The blood foam exiting from the return exchanger device flows through the surrounding defoamer filter, separating foam into blood fluid and exchanged gases. A relatively short fluid exchanger utilizes the additional blood foam residence time provided by the guidance channels. The tubular heat exchanger boundary case can have multiple fluid flow guidance fins linearly integrally disposed on the case exterior, parallel to the case tubular axis of symmetry and encircling the exterior case perimeter. The multiple guidance fins can have fin lengths extending from the top header plate to the multiple fin exit terminus, in part forming the multiple fluid flow guidance channels. Alternatively, a tubular return shell can have multiple fluid flow guidance channels interiorly disposed on the tubular shell wall, the guidance channels being disposed between adjacent pairs of fins integrally secured to the tubular shell parallel to the tubular axis of symmetry of the shell. The encircling fins

are disposed contiguous to the exterior of the exchanger tubular boundary case. The tubular return shell has a cap terminus disposed above a spaced holding chamber above the top header plate.

Another blood foam return device has an oxygenator tube 180° return loop extension of each fluid exchanger oxygenator tube and an oxygenator tube return length interiorly extending adjacently downward the internal perimeter of the tubular boundary case. An exit terminus on each return length imperviously extends through the boundary case, providing an exit for the blood foam into and through the surrounding annular defoamer filter. The U-bend exchanger tubes are temperature controlled by water or other heat transfer fluid circulating through the exchanger case.

Other objects and advantages of this invention are taught in the following description and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

A description of this invention is to be read in conjunction with the following drawings:

FIG. 1 is an elevational perspective partial sectional view of the blood foam return exchanger device.

FIG. 2 is another elevational perspective partial sectional view of an additional modification of the blood foam return exchanger device.

FIG. 3 is an elevation perspective partial sectional view of a portion of the integral blood oxygenator and heat exchanger disclosed and taught in the cited prior patent application, Ser. No. 240,054, including the modification of the blood foam return exchanger device shown in FIG. 1.

FIG. 4 is a sectional view through 4—4 of FIG. 3.

FIG. 5A is an enlarged sectional fragmentary view similar to the view of FIG. 4, illustrating the configuration of the blood foam return exchanger device of FIG. 1. FIG. 5B is a similar sectional view of the blood foam return exchanger device illustrated in FIG. 2.

FIG. 6 is an elevational perspective partial sectional view through another modification of the blood foam return exchanger device.

FIG. 7 is a sectional view through 7—7 of FIG. 6.

DESCRIPTION OF THE PREFERRED EMBODIMENT

A blood foam return exchanger device 10 is shown in FIG. 1 in elevational perspective view and discloses in part teachings incorporated in Ser. No. 240,054 and earlier cross-referenced patent applications. Multiple, small diameter oxygenator tubes 11 are shown in a patterned tubular array 12, whose length 13 has a base terminus 14 and a top terminus 15. A top and bottom pair of fluid impervious header plates 16 and 17 respectively secure the multiple tubes 11 in a tubular heat exchanger boundary case 18. The header plates 16 and 17 are secured in the case interior in a fluid exchange configuration. The tubular boundary case 18 has multiple fluid flow guidance fins 19 linearly disposed on the exterior of case 18 parallel to the case tubular axis of symmetry 36. The multiple guidance fins 19 are integrally secured to the tubular boundary case 18 on the exterior case perimeter. The multiple fins 19 have fin lengths extending from the top header plate 17 substantially to the multiple blood foam exit terminus 26, providing an additional blood foam residence time between the multiple fins 19, for completion of blood oxygenation at a required blood flow rate.

The return shell 20 adjacently closely fits exteriorly around and over the multiple guidance fins 19, the shell 20 having a shell length 27, completing the multiple blood foam exit terminus 26. The return shell 20 has a cap terminus 28 disposed above a spaced holding chamber volume 21, above the top header plate 17. Multiple fluid flow guidance channels 37 are thus provided by and between adjacent pairs of the fluid flow control fins 19 and the return shell 20.

As disclosed, taught and claimed in the above cross-referenced applications, a two-phase mixture of oxygen and blood is formed and introduced into the base of the oxygenator tubes 11. As schematically shown in FIG. 1, the blood 22 and the oxygen 23 form a two-phase blood foam mixture ascending the tubes 11 and flow into the spaced holding chamber 21. The return shell cap terminus 28 turns the blood foam flow downward 180°, and the blood foam 24 descends the multiple fluid flow guidance channels 37 in the flow direction indicated by the arrows 25. The defoamed blood 29 is filtered through the annular defoamer filter 30 and the exchanged gas 32, containing carbon dioxide, residual oxygen, and the like, exits through the upper section of the defoamer filter 30. Two filter tie cords 33 and 38 are shown securing the lower and upper terminus respectively of the filter 30, to the tubular case 18. As earlier disclosed in Ser. No. 240,054, the heat transfer fluid inlet conduit 34 introduces the heat transfer fluid, typically water, and the heat transfer fluid outlet conduit 35 conducts the temperature controlled heat transfer fluid out of the device 10.

FIG. 2 illustrates in detail another exchanger device modification, the blood foam return exchanger device 40. Multiple, small diameter oxygenator tubes 41 are shown secured in a patterned tubular array 42, having the length 43, a base terminus 44 and a top terminus 45. The base header plate 46 and the top header plate 47 secure the tubular array 42 of oxygenator tubes 41 in the tubular boundary case 48. A return shell 49 has multiple fluid flow guidance channels 50 interiorly disposed in the tubular return shell 49 wall. The multiple corrugated fins 51 disposed in adjacent corrugated fin pairs provide the guidance control channels 50. The tubular shell corrugated fins 51 are disposed parallel to the tubular axis of symmetry 61 of the shell, the fins 51 circumferentially disposed contiguous to the exterior of the tubular boundary case 48. The return shell 49 has a shell length 58. The shell cap terminus 59 is disposed above a spaced holding chamber volume 52, which is disposed above the top header plate 47, between the plate 47 and the cap 59. The multiple fin length can extend from the return shell terminus 57 upward to the cap terminus 59, or can terminate at the top terminus 45 of the fluid exchanger top header plate 47.

In operation, the two-phase mixture of blood 53 and oxygen 54 illustrated schematically in FIG. 2, form a two-phase mixture which flows in the noted direction up the multiple oxygenator tubes 41, exiting into the return chamber volume 52 as the blood foam 55. The blood foam 55 then returns downward along the paths denoted by the arrows 56 through the multiple fluid flow guidance channels 50, exiting from the channels at the foam blood exit terminus 60. The blood then exits into an annular defoamer filter similar to the filter 30 of FIG. 1, but not shown in FIG. 2. The heat transfer fluid inlet conduit 62 and exit conduit 63 respectively

corresponding to the conduits 34 and 35, are also illustrated in FIG. 2.

FIGS. 5A and 5B separately illustrate further modifications of the return shell 49 of FIG. 2. FIG. 5A illustrates the multiple oxygenator tubes 41 disposed in the interior of the tubular heat exchanger boundary case 48. The tubular return shell 49 is shown to have multiple corrugations therein providing multiple fluid flow guidance channels 50 interiorly disposed in the return shell 49 between the pair of fins 51, which are formed by narrow corrugations in the wall 49. Thus the fins 51 are formed by narrow corrugation apertures 67 which face outwardly from the wall 48 and channels 50 which face inwardly toward the wall 48. The inward facing channels 50 are the fluid flow guidance channels 50 for the flow of the two-phase mixture of blood foam. In FIG. 5B the wall 65 of the return shell 49' is shown to have integral solid fins 66 secured to the wall 65, fins 66 extending toward the tubular boundary case 48. A close fit can be provided between the fins 66 and the wall 48 providing controlled flow of blood foam in the guidance channels 50'.

The blood foam return exchanger device illustrated in one modification 10 in FIG. 1, and a second modification 40 in FIG. 2, FIG. 5A and FIG. 5B, can be formed of plastic material which is physiologically compatible with blood, from metal compatible with blood, and from non-toxic metal coated with an organic composition coating compatible with blood. In the blood foam return exchanger device combination illustrated in FIG. 1, the tubular boundary case 18 having multiple integral fluid flow control fins 19 can typically be a blood compatible plastic, or a metal structure coated with a blood compatible organic composition coating. A metal structure, coated with a thin organic coating, 0.001-0.002 inches thick, can provide a high heat transfer rate utilizing a typical water base heat transfer fluid. An integral plastic structure can also be provided which can have the advantage of being easy to fabricate.

Referring now to FIGS. 3 and 4 together in detail, a portion of an extra-corporeal blood oxygenator and blood temperature controller 70 is shown having a blood foam return exchanger device operationally disposed therein. The blood oxygenator and temperature controller is taught in the cross-referenced patent application Ser. No. 240,054 and earlier. Multiple small diameter oxygenator tubes 71 are shown disposed in a patterned tubular array 72, having equal tube lengths 73. The array has a base terminus 74 and a top terminus 75, the multiple tubes 71 being secured by a base header plate 76 and a top header plate 77, the plates being secured in the heat exchanger tubular boundary case 78. As similarly illustrated in FIG. 1, the multiple fluid flow guidance fins 79 integrally extend in parallel from the tubular case 78. The return shell 80 is shown closely fitting around the multiple fins 79, providing a holding chamber volume 81 disposed above the top header plate 77. The two-phase mixture of blood 82 and oxygen gas 83 are schematically shown entering the tubular array 72 adjacent the base header plate 76. Blood foam 84 exits from the tubes 71 adjacent the top header plate 77 into the chamber volume 81. The blood foam 84 flows downward the direction indicated by the arrow 85 in the multiple fluid flow guidance channels 109 to the return shell exit terminus 86 at the base of the return shell length 87. The return shell cap

terminus 88 provides a turning surface for the blood foam 84. The filtered defoamed blood 89 exits through the defoamer filter envelope 90. The exchanged carbon dioxide gas 92, including the residual oxygen gas and the like, escape through the upper portion of the foam filter envelope 90. The pair of foam filter collars 93 and the pair of compression rings 94 secure the foam filter envelope 90 and the filter cloth 91 to the heat exchanger tubular boundary base 78. The oxygenated filtered blood accumulates in the blood reservoir 100. The reservoir 100 is formed by the reservoir base closure 101, the exterior tubular case 102, and the case annular closure 105, as earlier taught in part in the application Ser. No. 240,054. The filtered blood accumulated in the reservoir 100 flows out in the direction 104 through the blood outlet conduit 103. The case annular closure 105 is a modification of the oxygenator closure 55 of the patent application, Ser. No. 240,054. As illustrated in FIG. 3, the annular closure 105, integrally secured to the return shell cap terminus 88, provides a top closure for the device 70. The return shell cap terminus 88 has an integral annular indexing flange 107 extending normally from the cap 88, with an integral vertical support ring 110 formed thereon. The filter cloth 91, which is exteriorly supportively disposed on the annular blood defoamer filter 90, terminates and is secured between the support ring 110 and the compressive filter cloth retainer ring 111. Thus the upper terminus of the annular defoamer filter 90 is permanently secured in position.

The lower Luer syringe aperture 108 provides means for introducing medicament into the blood accumulated in the reservoir 100. The aperture 106 is earlier disclosed in the above referenced patent application, providing means for the escape of exchanged gases 92 from the oxygenator device 70. As further disclosed in the earlier application, the heat transfer inlet conduit 95 is conductively secured to the boundary case 78, providing for the flow of the heat transfer fluid in the direction 98 into the device 70. The heat transfer agent exits through the water header conduit means 97, the water outlet manifold 99 and then through the water outlet conduit 96.

The closure means 112 comprises the top of the oxygenator device 70, and 112 comprises in combination the cap terminus 88, the annular closure 105, the annular indexing flange 107, and the integral vertical support ring 110.

Still another blood foam return fluid exchanger device is illustrated in FIGS. 6 and 7 together. The blood foam return exchanger device 150 has multiple small diameter oxygenator tubes 151 disposed in a patterned tubular array 152. The array 152 is similar in planar distribution to the array 72 of FIG. 3 and the like. The overall length of the multiple oxygenator tubes 151 have a controlled range of tube lengths extending from 153 to 154. The base 155 of the tubular array 152 has a base header plate 156, the header plate 156 being secured in the heat exchanger boundary case 157. Each one of the multiple oxygenator tubes 151 has an integral return loop 158 formed in a U-bend, amounting to an 180° angle. Each return loop 158 of one multiple oxygenator tube 151 is continuously integrally joined to one return length 159 of the oxygenator tube 151. The multiple return lengths 159 all terminate at substantially the same terminus line 186 level on the device 150. The multiple return length 159 extend downward

inside the boundary case 157 adjacent to the interior case perimeter, each one of the tubes 159 having a tube exit terminus 163 disposed downward through the case wall. The tube lengths 159 are fluid imperviously sealed to the case wall. As schematically illustrated in FIG. 6, the inlet blood 160 is mixed in a two-phase flow with the inlet oxygen 161 and introduced into the multiple oxygenator tubes 151 at the base header plate 156. The oxygenated blood foam 162 exits from each one of the oxygenator tube exit terminus 163. The filtered de-foamed blood is formed by passage through the annular blood defoamer filter combination of the annular defoamer 165 and the cloth filter 167. The defoamed blood is held in the blood collection reservoir 172. The annular defoamer 165 is secured by a first foam filter tie ring 166, and further secured by the cloth filter 167 which is additionally secured by the second tie ring 168. The top of the foam filter 165 and cloth filter 167 combination are secured in position by the first top closure 169. The first closure 169 also forms the top terminus of the heat exchanger 187.

The heat exchanger 187 can exchange energy with the blood foam disposed in the multiple oxygenator tubes 151. The heat exchanger 187 comprises the multiple oxygenator tubes 151, the base header plate 156, the first closure 169, the exchanger tubular boundary case 157, the water inlet conduit 176, and the water outlet conduit 179. Thus operationally the heat transfer fluid, typically water, flows in the inlet flow direction 177 and flows out of the heat exchanger in the direction 181. The water outlet conduit 179 has an internal exchanger terminus 180.

As disclosed in the above referenced application, the device 150 has a second top closure 182, a reservoir bottom closure 184, and an external tubular case 183, as previously disclosed. The blood outlet flow 173 is through the blood outlet conduit 175. As disclosed above, the exchanged gases escape upward through the annular gas escape chamber 170 through the annular defoamer filter 165 and the cloth filter 167 into the annular aperture 174, and thence out of the device 150 through the second top closure 182 as previously taught. The oxygenator component device 150, as taught above provides a further modification of the blood foam return exchanger device, having increased blood foam residence time in the oxygenator tubes in a compact device occupying relatively a short space and volume in a surgical operating room environment.

FIG. 7 illustrates in detail the relative positions of the multiple return loops 158 disposed in the patterned tubular array 152, which can provide for the patterned disposition of the multiple return lengths 159 of each one of the tubes 151, adjacent to the interior perimeter of the case 157. As illustrated, the return lengths 159 are disposed in a circular array around the perimeter of the patterned tubular array 152. FIG. 6 illustrates in elevational view and FIG. 7 illustrates in cross sectional view the positioning of the tiers of the multiple return loops 158. The multiple tube exit terminus 163 are disposed exteriorly through the case 157.

By incorporating the blood foam return exchanger device of this invention in combination with an extra-corporeal blood oxygenator and blood temperature

controller disclosed, taught and claimed in the cross-referenced applications, it is possible to reduce the length, typically 73 or the like, of the array of the multiple oxygenator tubes 71 or the like, since the blood foam is provided additional residence time in the blood foam return exchanger device for gas exchange. Further, the blood exchanges energy with the heat transfer fluid, such as water, as the blood foam rises in the patterned tubular array 72 or the like, and then further exchanges thermal energy as the blood foam descends in the direction 85 or the like in the blood foam return exchanger device. The additional residence time in the blood foam return exchanger device can provide blood foam counter flow for further precisely adjusting the blood foam temperature to the desired value, preventing fluctuation in blood temperature, which can be very undesirable. In those surgically selected cases where there is a requirement for induction of hypothermia, a metal fin structure can be incorporated in the blood foam return exchanger device as taught above, providing for a rapid controlled change of blood temperature, as is required. As a further advantage of this invention, the annular blood defoamer filter combination utilized with the invention filters from the bottom of the filter initially, rising toward the top of the filter as the filter pores become clogged. Thus the defoamed blood does not needlessly wash the unused filter until it is required. The filtered blood does not wet and stand in the un-required annular foam filter. The filtering of the blood foam initially at the base of the annular foam filter provides additional safety against the introduction of minute quantities of compositions which can produce undesired responses in the patient.

In illustration of the performance of the invention, a 25 kg weight dog test animal was perfused approximately 91 minutes, utilizing the extra-corporeal blood oxygenator and blood temperature controller incorporating the blood foam return exchanger device illustrated in FIG. 2. Initially, the test animal was sedated with Nembutal and cannulae bypass were inserted into the heart aorta and right atrium. The oxygenator was initially primed with 1,000 ml of Ringers lactate. Additional Ringers lactate and blood were added as required during the perfusion test. The essential data measuring the status of the dog are listed in Table I. The test animal was successfully maintained on the oxygenator of this invention for 90 minutes. Sustained pumped perfusion was maintained at an (O_2 vol./Blood vol) ratio ranging from a high of 3.33 down to 0.435. The successful perfusion at a ratio of 0.435 is particularly notable. The hemoglobin analysis of blood Samples 1 and 2 after 38 and 91 minutes on perfusion bypass indicate respective rates of hemoglobin mg percent of 0.97 and 0.48 mg percent/min. A rate of 1.0 mg percent/min is considered surgically acceptable. Two commercially available blood oxygenator devices have typical mg percent/min values of 1.3 and 2.5 respectively.

Many modifications and variations in the improvement in the blood foam return exchanger device can be made in the light of our teaching. It is therefore understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.

OXYGEN PERFUSION TEST

TIME	STATUS	BLOOD FLOW (l/min)	OXYGEN FLOW (l/min)	ARTERIAL pH	pO ₂ (min)	pCO ₂ (min)	HCT %	%O ₂ Saturate
1001	Pre-pump		—	7.54	381	18	43	99+
1030	Partial Oxygenator	1.8	6	—	—	—	—	—
1032	Complete oxygenator	2.1	5	—	—	—	—	—
1035	1st arterial blood sample	2.1	5	7.66	355	16.5	27	99
1035	1st venous blood sample	2.1	5	7.60	37	25.5	29	82
1056	2nd arterial sample	2.1	3	7.52	365	20	23	99
1056	2nd venous sample	2.1	3	7.46	37	30	28	77.4
1115	3rd arterial sample	2.1	3	7.55	371	20	24	99
1115	3rd venous sample	2.1	3	7.47	33	27	27	93.4
1134	4th arterial sample	2.1	4 *	7.29	410	39	25	99
1134	4th venous sample	2.1	4 *	7.27	43	42	—	76.6
1150	5th arterial sample	2.1	2.35 *	7.25	377	43	27	99+
1150	5th venous sample	2.1	2.35 *	7.23	45	48	28	72.4
1159	6th arterial sample	2.3	1	7.21	298	51	27	99
1159	6th venous sample	2.3	1	7.18	56	57	28	81
1201	Off pump							

* Used 95% O₂ + 5% CO₂

HEMOGLOBIN ANALYSIS

Laboratory Sample	Time on Bypass (min)	HEM (mg.%)	HEM/Min (mg %/min)
Sample 1	38	37.2	0.97
Sample 2	91	43.6	0.48
Normal			1.0

We claim:

1. In an extra-corporeal blood oxygenator and blood temperature controller having a patterned array of multiple, small diameter, equal length oxygenator tubes disposed in a top and a bottom pair of fluid-impervious header plates, useful for providing a blood foam composition in said multiple oxygenator tubes, the improvement comprising a blood foam return exchanger device combination comprising:

a tubular boundary case having a case interior, said base header plate, said top header plate and said multiple oxygenator tubes secured in said case interior, in a fluid exchanger configuration;

a means having multiple fluid flow guidance channels disposed adjacent the exterior of said tubular boundary case, providing guidance of said blood foam in a direction countercurrent to the flow of said blood foam in said multiple oxygenator tubes, said means having a return shell cap terminus disposed a spaced holding chamber volume above said top header plate, said means having a return shell length extending downwardly around and parallel to said fluid exchanger configuration providing multiple blood foam exit terminuses at a predetermined distance below said top header plate, said means providing a residence completion time for blood oxygenation at a required blood flow rate and blood temperature.

2. In an extra-corporeal blood oxygenator and blood temperature controller having a patterned array of multiple, small diameter, equal length oxygenator tubes disposed in a top and bottom pair of fluid-impervious header plates, wherein a blood foam composition can be formed in said multiple oxygenator tubes, the improvement comprising a blood foam return exchanger device combination comprising:

a tubular heat exchanger boundary case having a case interior, said base header plate, said top header plate and said multiple oxygenator tubes secured in said case interior in a fluid exchange configuration, said tubular case having multiple fluid flow guidance fins linearly disposed on the exterior of said boundary case parallel to the case tubular axis of symmetry and encircling the exterior case

perimeter, said multiple guidance fins integrally secured to said exterior case perimeter and having fin lengths extending from said top header plate to multiple fin exit terminuses at a predetermined distance below said top header plate; and,

a return shell adjacently fitting exteriorly around and over said multiple guidance fins, said return shell having a shell length providing multiple blood foam exit terminuses adjacent to said multiple fin exit terminuses, said return shell having a cap terminus disposed above a spaced holding chamber volume above said top header plate,

whereby said blood foam composition which can be formed in said multiple oxygenator tubes can flow into said spaced holding chamber volume, thence into the multiple fluid flow guidance channels provided between said return shell and said multiple fluid flow guidance fins and down through said multiple blood foam exit terminuses of said foam return fluid exchanger device.

3. The blood foam return exchanger device of claim 2 in which said tubular heat exchanger boundary case is formed from a non-toxic metal having a thin organic composition coating disposed completely over the face of said case exposed to said blood foam, said coating being physiologically compatible with said blood foam.

4. The blood foam return exchanger device of claim 2 in which said return shell is formed from a plastic composition, physiologically compatible with said blood foam.

5. The blood foam return exchanger device of claim 2 having an annular blood defoamer filter loosely spaced completely circumferentially around said return shell, said filter having one perimeter terminus secured to said tubular boundary case adjacently below said multiple fin exit terminuses, and said filter having a second perimeter terminus secured to said return shell adjacent to said return cap terminus.

6. In an extra-corporeal blood oxygenator and blood temperature controller having a patterned array of multiple small diameter, equal length oxygenator tubes disposed in a top and a bottom pair of fluid-impervious header plates, providing a blood foam composition in

said multiple oxygenator tubes, the improvement comprising a blood foam return exchanger device combination comprising:

- a tubular heat exchanger boundary case having a case interior, said base header plate, said top header plate and said multiple oxygenator tubes secured in said case interior in a fluid exchanger configuration; and,
- a tubular return shell adjacently fitting circumferentially around said fluid exchanger configuration, said return shell having multiple fluid flow guidance channels interiorly disposed on the tubular shell wall, said guidance channels disposed between adjacent pairs of fins integrally secured to said tubular shell parallel to the tubular axis of symmetry of said shell, said fins encirclingly disposed contiguous to the exterior of said tubular boundary case, said fins having fin lengths extending from at least said top header plate to multiple fin exit terminuses at a predetermined distance below said top header plate, said tubular return shell having a cap terminus disposed above a spaced holding chamber volume above said top header plate, said multiple fin length providing a blood foam residence time between said fins for completion of blood oxygenation at a required blood flow rate and blood temperature.

7. The blood foam return exchanger device of claim 6 in which said tubular return shell is formed from a non-toxic metal having a thin organic composition coating disposed completely over the face of said shell exposed to said blood foam, said coating being physiologically compatible with said blood foam.

8. The blood foam return exchanger device of claim 6 in which said tubular return shell is formed from a plastic composition, physiologically compatible with said blood foam.

9. The blood foam return exchanger device of claim 6 having an annular blood defoamer filter loosely spaced completely circumferentially around said return

shell, said filter having one perimeter terminus secured to said tubular boundary case adjacently below said multiple fin exit terminuses of said tubular return shell and said filter having a second perimeter terminus secured to said return shell adjacent said return cap terminus.

10. In an extra-corporeal blood oxygenator and blood temperature controller having a patterned array of small diameter oxygenator tubes disposed in a bottom fluid-impervious header plate, and a heat exchanger tubular boundary case securing said header plate in the boundary case base, the improvement comprising a blood foam return exchanger device combination comprising:

- said multiple oxygenator tubes having a controlled range of tube lengths, each one of said tubes having a 180° U-bend at the upper extremity thereof, each one of said tubes having a return length extending downwardly inside said exchanger case adjacent to the interior perimeter of said case, each one of said tubes having a tube exit terminus disposed downwardly, through the exchanger case wall and fluid imperviously sealed to said wall, all said exit terminuses disposed at substantially the same terminus line level of said case;

a closure securing the top of said heat exchanger case;

means for conducting a heat transfer fluid through said heat exchanger case;

an annular blood defoamer filter spaced circumferentially around said heat exchanger case and said multiple tube exit terminuses, said filter having one perimeter terminus conductively sealed to said exchanger case adjacently below said case closure, and said filter having the second perimeter terminus conductively sealed to said oxygenator below said terminus line level so that blood foam exiting from said multiple tube exit terminuses must pass through said defoamer filter.

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